

GAS RELIEF- simethicone capsule, liquid filled
PuraCap Pharmaceutical LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

GAS RELIEF

Drug Facts

Active ingredient (in each softgel)

Simethicone 125 mg

Purpose

Antigas

Uses

for the relief of

- pressure, bloating, and fullness commonly referred to as gas

Warnings

Keep out of reach of children.

Directions

- adults: swallow with water 1 or 2 softgels as needed after meals and at bedtime
- do not exceed 4 softgels in 24 hours except under the advice and supervision of a physician

Other information

- store at room temperature 15°-30°C (59°-86°F)
- protect from light, heat and moisture

Inactive ingredients

D&C yellow #10, FD&C blue #1, FD&C red #40, gelatin, glycerin, peppermint oil, purified water, white edible ink

Questions or comments?

Call toll free: **1-800-833-6278**

PRINCIPAL DISPLAY PANEL

EXTRA STRENGTH GAS RELIEF

SIMETHICONE 125 mg ANTIGAS 30 Softgels

NDC 51013-109-10

*Compare to the active ingredient in Gas-X[®] Extra Strength Softgels



EXTRA STRENGTH GAS RELIEF
 SIMETHICONE 125 mg ANTIGAS 50 Softgels
 NDC 51013-109-09

*Compare to the active ingredient in Gas-X[®] Extra Strength Softgels



GAS RELIEF

simethicone capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51013-109
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	125 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	green (opaque)	Score	no score
Shape	capsule (oval)	Size	10mm
Flavor		Imprint Code	PC2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:510 13-109-10	3 in 1 CARTON	07/13/2016	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:510 13-109-09	5 in 1 CARTON	07/13/2016	
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part332	07/13/2016	

Labeler - PuraCap Pharmaceutical LLC (962106329)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(510 13-109) , analysis(510 13-109)

Revised: 7/2016

PuraCap Pharmaceutical LLC